4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1226]

Howard Stanley Head, Jr.: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Howard Stanley Head, Jr. for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Head was convicted of one felony count under Federal law for conspiracy to import misbranded prescription drugs. The factual basis supporting Mr. Head's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Head was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 24, 2022 (30 days after receipt of the notice), Mr. Head had not responded. Mr. Head's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On November 2, 2021, Mr. Head was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Eastern District of Kentucky-Central Division of Frankfort, when the court entered judgment against him for the offense of conspiracy to import misbranded prescription drugs, in violation of 18 U.S.C. 371. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows:

As contained in the indictment, filed on November 5, 2020, and in the plea agreement in Mr. Head's case, filed June 10, 2021, in or about June 2015 and continuing through October 2019, Mr. Head conducted a business under the name "Dr. Head's Meds." In conducting this business, on multiple occasions Mr. Head purchased thousands of generic medication tablets for erectile dysfunction from overseas suppliers located in countries such as India and Singapore. At his request, these suppliers sent packages containing generic versions of VIAGRA and CIALIS to Mr. Head's residence and other locations via the U.S. Postal Service. The labeling accompanying these packages described their contents in an inaccurate or misleading manner, such as "Supplement." After receiving the bulk shipments of generic erectile dysfunction tablets, Mr. Head sold them in smaller quantities to customers in the United States.

As a result of this conviction, FDA sent Mr. Head, by certified mail, on January 21, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of

the FD&C Act that Mr. Head's felony conviction under Federal law for conspiracy to import misbranded prescription drugs, in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported and introduced misbranded prescription drug products into interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Head's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Head of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. U.S. Postal Service records indicate that after a delivery attempt to Mr. Head's residence was made and a notice left, the proposal and notice of opportunity for a hearing letter was picked up at his local post office on February 22, 2022. Mr. Head failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Howard Stanley Head, Jr. has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Head is debarred for a period of five years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for

import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Head is a prohibited act.

Any application by Mr. Head for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-1226 and sent to the Dockets Management Staff (see ADDRESSSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: May 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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